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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,079	01/21/2000	Patricia A. Billing-Medel	6451.US.P1	5338

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,079	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-06-03 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 52-61, 70, and 77-81, drawn to the elected invention in Paper # 7, are currently under examination. Additionally, claims 62-69 and 71-76 will be joined with the elected invention since these claims were amended to read on the elected invention.

Response to Arguments

4. Claims 52-61, 70, and 77-81 remain rejected, and claims 62-69 and 71-76 are rejected under 35 USC § 101 and 112, first paragraph, for the reasons of record set forth in the Official Action mailed 5-16-02.

5. Applicant's arguments filed 11-06-03 have been fully considered but they are not fully persuasive. Applicants traverse the instant rejection on the grounds that the Jager et al. article cited by Applicants, supports Applicants' contention that SEQ ID NOS: 24-28 as claimed are useful as required by 35 USC § 101 and § 112, 1st pargraph. According to Applicants, because there is over one thousand nucleotides identical between the BS322 nucleic acid and the nucleic acid encoding NY-BR-1, this evidence of similarity between the two sequences clearly provides

evidence that BS322 is a splice variant of NY-BR-1. However, contrary to Applicant's assertions it is noted that Jager et al. describes the identification of two NY-BR-1 splice variants (see page 2058, and Figure 3), wherein the two sequences differ only by the presence of an additional coding sequence of 111 bp in one splice variant, and is absent in the other variant. There is no evidence of an additional splice variant that produces polypeptides according to SEQ ID NO: 24-28 of the instant invention. Applicants consistently refer to the similarity between the polynucleotide sequences of the BS322 consensus sequence (SEQ ID NO: 9) and NY-BR-1, however the instant claims are drawn to the polypeptides according to SEQ ID NO: 24-28.

Applicants have not provided any objective evidence that would demonstrate that the individual peptides according to SEQ ID NO: 24-28 represent actual NY-BR-1 antigen epitopes such that antibodies targeting these peptides could be potentially useful detecting disease in breast or used in a method for treating breast cancer, as suggested by Applicants on page 1, paragraph 1 of the specification as filed. The Jager et al. reference states that antibody probes must be produced in order to confirm breast specificity of NY-BR-1 at the protein and cell levels, see page 2059 of Jager et al., 2nd col. 2nd paragraph. Therefore, although the Jager et al. may provide evidence that the polynucleotides of the present invention may be useful as a breast or testis specific probe, Jager et al. does not provide any objective evidence that the NY-BR-1 protein or the polypeptides according to SEQ ID NO: 24-28 of the instant invention are breast specific or breast tumor specific antigens, such that antibodies targeting NY-BR-1 or BS322 could potentially be useful for the detection of disease of the breast or used in a method for the treatment of breast cancer.

Furthermore, Applicants have not provided any evidence that the relative mRNA abundance of the BS322 transcript encoded by SEQ ID NO: 9, in breast tissue would be predictative of the corresponding relative abundance of the BS322 polypeptides in breast tissue. It is well known in the art that there is no direct correlation between mRNA abundance and protein abundance, see for example Anderson et al. (1997), page 537, and Gygi et al. (1999), abstract. As stated above, although Jager et al. may provide evidence that the polynucleotides of the present invention may be used to identify the tissue specific expression of NY-BR-1, one of skill in the art would not accept on its face that such evidence is sufficient to support the utility of the claimed polypeptides as breast specifc antigens that are useful as diagnostics for breast disease. The arguments provided by Applicants are clearly speculative, and not supported by objective evidence.

6. Claims 62-68 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 52-58. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. Claims 72-76 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 52-56. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 77-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 77 recites "[A] method for detecting at least one specific for a BS322 antigen." The metes and bounds of this phrase are vague and indefinite since it is unclear what "at least one," refers to as stated in the context of this claim. One of ordinary skill in the art would not be able to ascertain the scope of the claimed invention due to the ambiguity associated with the language cited above.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 57-59, 61, 67-69, 71, 77-79 and 81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

The instant claims are drawn to methods comprising the use of BS322 polypeptides containing at least one BS322 epitope derived from an amino acid sequence selected from the

group consisting of SEQ ID NO: 24-28. According to the specification as filed the BS322 epitopes of the invention comprises an amino acid having at least 50% identity to the polypeptides of the present invention encoded by BS322 (see the specification as filed, page 9, lines 22-24). However, the BS322 polypeptides of the claimed invention encompass proteins that are not adequately described by the specification as filed, since neither the claims nor the specification as filed indicate what distinguishing structural or functional attributes the members of the claimed genus of polypeptides share. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claim polypeptides, it is only required that a BS322 polypeptide contains at least 50% identity to the polypeptide sequences according to SEQ ID NO: 24-28. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members are permitted, and neither the specification nor the claims provide any guidance as to what specific changes should be made. Furthermore, there are no common functional attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, the disclosed sequences of SEQ ID NO: 24-28 alone are not sufficient to describe the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE